PTO/SB/08a (05-07)
Approved for use through 09/30/2007 OMB 0851-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE to a collection of information unless it contains a valid OMB control number. Under the Paperwork Reduction Act of 1995, no persons are required to

| INFORMATION DISCLOSURE |
|---|
| STATEMENT BY APPLICANT |
| (Not for submission under 37 CFR 1.99) |

| Application Number | | 10684226 | | |
|--|------|-------------|--|--|
| Filing Date | | 2003-10-10 | | |
| First Named Inventor RUTI- Art Unit | | HERFORD | | |
| | | 3732 | | |
| Examiner Name | Cary | E. O'Connor | | |
| Attorney Docket Number | | 32087/1010 | | |

| | | | | | U.S. | PATENTS | | | Remove | | |
|-----------------------|------------|--|------------------------------|-----------------|---------------------------|-------------------------------|---|----------|--|-----------------------------|----|
| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue E | Date | Name of Pate of cited Docu | entee or Applicant ment | Releva | | Lines where ges or Relev | |
| | 1 | | | | | | | | | | |
| If you wisi | h to a | dd additional U.S. Pate | nt citatio | n inform | ation pl | lease click the | Add button. | | Add | | |
| | | | U.S.P | ATENT | APPLI | CATION PUB | LICATIONS | | Remove | | |
| Examiner Initial* | Cite No | Publication Number | Kind Code ¹ | Publica Date | tion | Name of Patentee or Applicant | | Releva | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | | |
| | 1 | | | | | | | | | | |
| If you wisl | h to a | dd additional U.S. Publi | shed Ap | plication | citatio | n information p | lease click the Ad | d button | _ | | |
| | | | | FOREIG | GN PA1 | ENT DOCUM | ENTS | | Remove | | |
| Examiner Initial* | Cite No | Foreign Document Number ³ | Country Code ² | | Kind Code ⁴ | | Name of Patente Applicant of cited Document | or , | vhere Rel | or Relevant | т. |
| | 1 | | | | | | | | | | С |
| If you wish | h to a | dd additional Foreign P | atent Do | cument | citation | information pl | lease click the Add | button | Add | | _ |
| | | | NON | I-PATE | NT LITE | RATURE DO | CUMENTS | | Remove | | |
| Examiner Initials* | Cite No | Include name of the a (book, magazine, jour publisher, city and/or | nal, seria | al, symp | osium, | catalog, etc), o | | | | | T |

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

| oplication Number | | 10684226 |
|-------------------------|--|-------------|
| ling Date | | 2003-10-10 |
| rst Named Inventor RUTH | | IERFORD |
| t Unit | | 3732 |
| caminer Name Cary E | | E. O'Connor |
| tomou Docket Number | | 32087/1010 |

| | 1 | GIUSTI et al., "New Biolized Polymers for Cardiovascular Applications," Life Support Syst. 3(Suppl 1) 476-80 (1985). | | | | | |
|---|---|--|--|--|--|--|--|
| | 2 | MERRILL, "Poly(Ethylene Oxde) Star Molecules: Synthesis, Characterization, and Applications in Medicine and Biology," J. Biomater. Soc. Polym. Ed. 5(1-2):1-11 (1993). | | | | | |
| | 3 | RICORDI et al., "Renal Subcapsular Transplantation of Clusters of Hepatocytes in Conjunction with Pancreatic Islets," Transplantation 45(6):1143-51 (1988). | | | | | |
| | 4 | SCHMOLKA, 'Artificial Skin. I. Preparation and Properties of Pluronic F-127 Gels for Treatment of Burns," J. Biomed. Mater. Res. 6(6):571-82 (1972). | | | | | |
| | 5 | VACANTI et al., "Tissue-engineered Growth of Bone and Cartilage," Transplantation Proc. 25(1):1019-21 (1993). | | | | | |
| If you wish to add additional non-patent literature document citation information please click the Add button Add | | | | | | | |
| EVANIMED CICHATUDE | | | | | | | |

F

E

Examiner Signature Date Considered

EXAMINER: nitial inference considered, whether or not citation is in conformance with MPEP 699. Draw line through a citation in find nonformance and not considered, include copy of this form with next communication to applicant.

16e Kind Code of USPTO Potent Documents at even USPTO_CODY or MPEP 901.04. 2 fitter of tice that issued the document, by the Involved the OWIPO Standard ST3.) 3 for Usual passes patient fourants, the involved to office the proper or the Empirer or may refer be seen or the pasted document. 4 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST1.6 if possible. 2 Applicant is to place a check marx here if Empire Indiquage the installation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

| Application Number | | 10684226 |
|------------------------|------------------|------------|
| Filing Date | | 2003-10-10 |
| First Named Inventor | RUTH | IERFORD |
| Art Unit | | 3732 |
| Examiner Name | Cary E. O'Connor | |
| Attorney Docket Number | | 32087/1010 |

CERTIFICATION STATEMENT

| Please see 37 | CFR 1.97 and | 1.98 to make the appropriate selection(s): |
|---------------|--------------|--|
|---------------|--------------|--|

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patient office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. Sea 37 CFF 1.37(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office is a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquity, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 175(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 179(10).

- See attached certification statement.
- Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ▼ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| Signature | /Shelley A. Jones/ | Date (YYYY-MM-DD) | 2007-07-26 |
|------------|--------------------|---------------------|------------|
| Name/Print | Shelley A. Jones | Registration Number | 53,081 |

This collection of information is required by 3T CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is for life railed by the USPTO to process) an application. Confidentiality is governed by \$5 U.S. C. 12.0 and 3T CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application from the USPTO. Time will vary depending upon the individual case: Any comments on the amount of time you require to complete his form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. operatment of Commence, P.O. 8bx 1445, Alexandrin, V.S. 2311-1450, D.O. NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. 8bx 1459, Alexandria, V.S. 2311-1450.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the stacked form related to a petient application or patient. Accordingly, pursuant to the requirements of the Act, please be advised that (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) familishing of the information solicided is civulating; and (3) the principal purpuse for which the information is used by the U.S. Patient and Trademan Coffice is to process and/or cosmisting your submission related to a patient agricultant or patient. If you do not furnish the requested process and/or cosmisting your submission related to a patient agricultant or patient. If you do not furnish the requested process and the process of the process and the process of the pro

The information provided by you in this form will be subject to the following routine uses:

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these cords.
 - A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
 - A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record perfains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
 - A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552(m).
 - A record related to an International Application filed under the Patent Cooperation Treaty in this system of records
 may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant
 to the Patent Cooperation Treaty.
 - A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
 - 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or hisher designed, uturing an insection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 4d U.S.C. 2904 and 2905. Such disclosure shall be made in accordance with the GSA requisions governing inseption of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- A record from this system of records may be disclosed, as a routine use, to the public after either publication of the
 application pursuant to 35 U.S.C. 12(2) to rissuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be
 disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filled in application
 which became abandoned or in which the proceedings were terminated and which application is referenced by either a
 published application, an application open to public inspections or as issued patent.
 - A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.